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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/887,318 | 06/21/2001 | James W. Ayres | 245-59204 | 6784 |

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| EXAMINER |
|---|
| OH, SIMON J |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/887,318 | AYRES, JAMES W. | |
| | Examiner | Art Unit | |
| | Simon J. Oh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-87 is/are pending in the application.

4a) Of the above claim(s) 35-57, 60-62, 64-72, 74-78, and 81 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-87 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Upon consideration of the applicant's Response to Restriction Requirement of 24 September 2002, non-elected Groups II and III will be combined into a single group, but will still be considered to be withdrawn from consideration. Prosecution will advance in this present office action on the elected claims of Group I.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 16, 17, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "greater than 25% of an expandable material" renders the claim indefinite because it is unclear what is meant by the percentage figure. The examiner requests clarification as to what kind of percentage is intended (i.e., weight, volume, molar) and percentage of which physical property or parameter (i.e., of the entire tablet, or the core alone, or of the total of the active ingredients, etc.).

Claims 16 and 17 recite the limitation "the n value" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the belly band" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 9, 10, 19, 20, 22, 82-84, 86, and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Balken *et al.* (U.S. Patent No. 6,183,780 B1)

The Van Balken patent teaches oral dosages forms with delayed immediate-release characteristics, in which an active agent is released from a core upon rupture of an outer coating covering the dosage form (See Abstract). The core contains the active agent and common fillers, and binders. Preferably, a small amount of a swellable material, such as cross-linked carboxymethylcellulose is added to this core (See Column 3, Lines 32-45). The coating material may be selected from materials, such as ethylcellulose and other water-insoluble cellulose derivatives, and polymethacrylates (See Column 4, Lines 19-23). The coating material also comprises a water-soluble plasticizer and a brittleness-inducing agent (See Column 3, Lines 58-

61; and Column 4, Lines 30-53). The delayed immediate-release dosage form may be also coated with more than one coating materials, and be surrounded with an immediate release formulation (See Column 6, Lines 14-37; and Claim 16). Various release profiles may be achieved with the disclosed dosage form, including one that substantially corresponds to the limitations concerning the active agent release profile of Claim 15 (See Figure 5). Various lag times for the release of the active agent may also be achieved (See Figures 6 and 7).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34, 58, 59, 63, 73, 79, 80, and 82-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Balken *et al.* in view of Wong *et al.* (U.S. Patent No. 6,120,803)

The relevant details of Van Balken *et al.* are given in the above rejection of Claims 1, 2, 9, 10, 19, 20, 22, 82-84, 86, and 87 under 35 U.S.C. 102(e). Van Balken *et al.* do not teach the use of a banded dosage form.

Wong *et al.* teaches a dosage form adapted for retention in the stomach, comprising a polymer matrix and a band of insoluble material that acts to control the swelling of a portion of the polymer matrix, delaying expulsion of the dosage form from the stomach until substantially all of the active agent has been dispensed (See Abstract; Column 5, Lines 10-27; Column 11, Lines 40-58; and Column 16, Lines 9-27). Polymers suitable for use in the matrix include

hydroxypropylmethylcellulose, carboxymethylcellulose, and pectins (See Column 5, Line 55 to Column 6, Line 2). The dosage form is suitable for use with a variety of active agents, including glipizide (See Column 18, Line 33). Alternative embodiments are disclosed, including one formed with an outer layer comprising an active agent (See Column 20, Lines 35-60). Gastric platform dosage forms are included within the scope of the disclosure, including one form in which the matrix is subcoated, banded, and then overcoated (See Column 27, Example 8). The disclosed dosage form dispenses an active agent at a substantially constant rate of release (See Figures 8 and 9)

It would be obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Van Balken *et al.* and Wong *et al.* into the objects of the instant application. The invention of Van Balken *et al.* is directed to a dosage form in which the release of the active agent is delayed for one hour to several hours. The invention of Wong *et al.* features a banded tablet in which expulsion of the dosage form from the stomach is delayed until nearly all of the active agent has been dispensed. Thus, one of ordinary skill would be motivated, with a reasonable expectation of success, to combine the two references in order to create a dosage form that ensures gastric retention for an extended period of time that equals or exceeds the sum of first, the desired lag time of the release of the active agent and second, the time necessary to dispense a substantial portion of the active agent from the core of the dosage form.

Claim limitations of Claims 11, 12, 23, and 24 directed to specific features of the claimed belly band are not considered to be critical by the examiner in view of the disclosure of the prior

art. The examiner shifts the burden onto the applicant to provide a showing of criticality or of unexpected results that would distinguish the claimed invention above the prior art.

Because Claims 58, 59, and 63 are drawn to tablets and are therefore composition claims, claim limitations concerning the specific rupturing action of the membrane are not given patentable weight.

In view of the disclosure of the prior art where the lag-time of the release of the active agent from the dosage form of the Van Balken *et al.* patent is capable of exceeding 6 hours, and the release of the active agent from the dosage form of the Wong *et al.* patent can occur over a period of time approaching 12 hours, methods of administration of a dosage form of the combined disclosures in a once-a-day or twice-a-day formulation are obvious. Furthermore, such methods of administration may be obtained by routine experimentation by one of ordinary skill in the art.

Claims 16, 17, 26, 27, and 30-34 contain claim limitations that characterize the release of the active agent during a portion of the drug release profile in terms of a parameter called the n value. From the applicant's disclosure, the examiner interprets these limitations to characterize a near-zero-order rate of release. That is, a release rate which remains substantially constant for a significant portion of the drug release profile. However, in view of the disclosure of the release profiles in Wong *et al.* (See Figures), the examiner does not find a patentable distinction in these claims that would elevate them above the prior art.

Thus, the claimed invention is *prima facie* obvious.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
December 16, 2002

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600